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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.				
10/510,068	10/04/2004	Stanley F Barnett	21075YP	5599				
210 MERCK AND CO., INC P O BOX 2000 RAHWAY, NJ 07065-0907	7590 07/17/2007		<table border="1"><tr><td colspan="2">EXAMINER</td></tr><tr><td colspan="2">SUTTON, DARRYL C</td></tr></table>		EXAMINER		SUTTON, DARRYL C	
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No. 10/510,068	Applicant(s) BARNETT ET AL.	
	Examiner Darryl C. Sutton	Art Unit 1609	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10/04/2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-55 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-55 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 1-41 and 47-55 drawn to methods of treating cancer in a mammal comprising administering a selective inhibitor of the activity of one or more of the isoforms of Akt.

Group 2, claim(s) 42-43, drawn to methods of identifying a selective inhibitor compound.

Group 3, claim(s) 44, drawn to a modified isoforms of Akt lacking only the PH domain.

Group 4, claim(s) 45, drawn to a modified isoforms of Akt lacking only the hinge region.

Group 5, claim(s) 46, drawn to a modified isoforms of Akt lacking the full PH domain and the full hinge region.

The inventions listed as Groups 1, 2, 3, 4 and 5 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: There is no common special technical feature between inventions, since Group 1 claims an inhibitor of the activity of one or more isoforms of Akt for the treatment of cancer, while Groups 3, 4 and 5 claim actual modified isoforms of Akt. Therefore, there is a lack of unity.

This application contains claims directed to more than one species of the generic inventions. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Group 1, drawn to methods of treating cancer in a mammal comprising administering a selective inhibitor of the activity of one or more of the isoforms of Akt. Each method claim contains a separate species of one or more isoforms of Akt that will be inhibited. Since each isoform of Akt is overexpressed in different tissue throughout the body (Masure et al. Eur. J. Biochem, 1999), their inhibition would inhibit the growth of tumors of different cancers. For example, Akt1 is highly expressed in human breast carcinoma cell lines (Ahmad, et al., 1999, Biochem. Pharmacol.), while Akt2 is overexpressed in ovarian carcinomas (Cheng et al., Proc. Natl. Acad. Sci., 1992). Applicant is required to select a species of inhibitor, i.e. an inhibitor of Akt1, inhibitor of Akt2, inhibitor of Akt3 or the inhibitor of any of the claimed combinations of Akt1, Akt2, and Akt3. Furthermore, for examination purposes, if claims 47 or 49-55 are selected as species, the applicant is required to select a species of the second compound that is administered in conjunction with the inhibitor. The choice of second compound is from a list of compounds that have different and distinct physiologically affects on the body.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims

subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

### ***Conclusion***

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darryl C. Sutton whose telephone number is (571)270-3286. The examiner can normally be reached on M-Th from 7:30 AM to 4:45 PM and Fr from 7:30 AM to 4:45 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker, can be reached on M-Th from 7:30 AM to 4:30 PM at (571)272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

DCS

A handwritten signature in black ink, appearing to read 'M. Meller', with a long horizontal flourish extending to the right.

**MICHAEL MELLER  
PRIMARY EXAMINER**